US ERA ARCHIVE DOCUMENT

Comment: OBJ

# TSS/IRB PRECAUTIONARY LABELLING REVIEW

Introcunation winds may covered most incort incort incorts is not included

# BACKGROUND

- 1. Application to increase dosage rate of a previously registered product.
- 2. See previous reviews (6/29/84 and correspondence) concerning reports of adverse effects and safety data for cats.

### **USES**

Dogs, cats, puppies and kittens. 1.5-2.5 oz/gallon of water. Dip, sponge on, pour on.

### SUBMITTED DATA

- A. Data not accessioned. Hooser, Beasley, and Everitt, National Animal Poison Control Center, University of Illinois, 1-10-85 Final Report on an Evaluation of the acute toxicity of a Commercial Dip containing d-limonene in the Feline Animal.
- 1. See previous protocol review.
- 2. Part A. 1 M and 1 F cat per dose level. Range finding study.

Dose	Results
lX (1.5 oz/gal)	Unremarkable
4X	1/2 salivation for 30 min. eye irritation
8X	2/2 salivation, muscle tremors, ataxia, 3 hours.
16X	2/2 salivation, tremors, shivering, scrotal irritation.
water control	Unremarkable
control	Unremarkable

Part B. 4 M and 4 F cats per dose.

Dose	Results
1x	1/8 15 min. salivation. 2/8 tremors for 15 min. No Temperature decrease.
5x `	8/8 salivation, 8/8 tremors for 1-3 hours. 5/8 ataxia, Mild hypothermia, -2.5°F. 1/4 M scrotal irritation.
15X	8/8 salivation for 15 min-1 hour. 8/8 muscle tremors 1-4 hours. Ataxia for 5 hours. eye irritation when accidentally introduced. hypothermia -7.5° for 5 hours. 4/4 males lost hair from scrotal areas.
water control	-0.5°F
Vehicle control	+0.5°F

Part C. 1 immature cat per dose. Results as above.

## CONCLUSIONS

- 1. The submitted toxicity study for cats is noted.
- 2. The proposed rate change is acceptable.
- 3. The mechanism of the induction of hypothermia by this product should be investigated. Does linalcol produce similar reactions?

#### LABELLING

- A. The submitted labelling is not acceptable.
- 1. Change the precautionary statements to:

May cause eye injury. Do not get in eyes or on clothing. Wear safety glasses. Harmful if swallowed. Wash thoroughly with soap and water after handling.

Use with caution on nursing animals. Do not use on puppies or kittens under 6 weeks of age.

Some individuals and pets may be sensitive to this product. If irritation developes, discontinue use.

- 2. Place "do not use full strength" in the directions for use.
- 3. Add "scrotal and anal" to the "avoid eye area" statement.
- 4. To the dilution graph specify the amount of water (per gallon).
- 5. It is suggested that alternative units of measure be added to the dilution graph. (ie. 3,4,5, tablespoons per gallon).
- 6. As full immersion is not one of the recommended methods of application for this product (and is probably unadvisable), the name should be changed to prevent the user from whole body immersion which could result in irritation to some areas of the body. Suggested names would be something like sponge-on, sponge dip, etc.

Phil Hutton TSS/IRB